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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,907	11/20/2006	Graham Mcintyre	15131.0003	6019

27890 7590 03/22/2007

STEPTOE & JOHNSON LLP
1330 CONNECTICUT AVENUE, N.W.
WASHINGTON, DC 20036

EXAMINER	
SWARTZ, RODNEY P	
ART UNIT	**PAPER NUMBER**
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,907	MCINTYRE ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *5-11 and 16-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 12-15* is/are rejected.

7)☒ Claim(s) *13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *1May2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/1/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' Preliminary Amendment, received 1 May 2006, is acknowledged.

Claims 1-25 are pending. Claims 5-11 and 16-25 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from a multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 5-11 and 16-25 have not been further treated on the merits.

2. Claims 1-4 and 12-15 are under consideration.

Specification

3. The disclosure is objected to because of the following informalities:

Page 3, line 10, "immunising" should be "immunizing"; line 14, insert (immediately prior to George; line 23, insert (immediately prior to Mukherjee and delete the (immediately prior to *Thromb*; line 31, "internalisation" should be "internalization"

Page 11, line 5, , "immunising" should be "immunizing".

Page 13, line 1, "ionising" should be "ionizing"; lines 20-21, what is meant by "where there is is more than one does"?

Page 22, line 14, delete one of the periods at the end of the sentence.

Page 24, line 3, "solubilising" should be "solubilizing"; line 5, "stabilisers" should be "stabilizers".

Page 29, line 26, "corprophilus" should be "coprophilus".

Page 33, the units of measure listed in Table 1 should be included in the Table.

Page 35, the units of measure listed in Table 2 should be included in the Table.

Page 36, line 22, "in duration" should be "induration".

Page 41, line 1, "immunisation" should be "immunization"; line 21, "the_hind" should be "the hind".

Page 42, line 20 "immunisations" should be "immunizations"; line 22, "immunisation" should be "immunization".

Page 46, line 25 to page 47, line 13, what are the units of measure?

Page 50, lines 10-16, what are the units of measure?

Page 51, line 18, "*inchinensis*" should be "*inchonensis*".

Page 52, line 16, "standardised" should be "standardized".

Page 59, line 27, "immunising" should be "immunizing".

Page 60, line 19, "internalisation" should be "internalization"; line 25, "recognisable" should be "recognizable".

Page 61, lines 4, 8, 14, "randomised" should be "randomized".

Page 62, line 19, "randomising" should be "randomizing"; line 26, "randomisation" should be "randomization".

Page 63, fourth box in Table, "Randomisation" should be "Randomization".

Page 65, line 5, "Alliquots" should be "Aliquots".

Appropriate correction is required.

Drawings

4. Figures 3, 4, 5, 6, 7, 8, 9, and 10 are objected to under 37 CFR 1.83(a) because they fail to show the units of swelling. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet

should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action.

The objection to the drawings will not be held in abeyance.

Claim Objections

5. Claim 13 is objected to because of the following informality: line 1, "immunising" should be "immunizing". Appropriate correction is required.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1-4 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-4 provide for the use of a composition, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

10. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is meant by "wherein the autoimmune or of the myocardium disease or autoimmune disorder involves"

11. Claims 12-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for: 1) methods of altering thickening of the intimal layers of the common carotid artery of rats following balloon angioplasty utilizing injections of *B. bronchialis, R. coprophilus, T. inchonensis, or M. vaccae*, and 2) altering the levels of BCG skin reactions, does not reasonably provide enablement for the extremely broad scope of the instant claims, i.e., method for treating or preventing any/all autoimmune diseases or disorders. The specification does not enable any person skilled in the art to which it pertains, or with which it is

most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention is method for treating or preventing any/all autoimmune diseases or disorders utilizing injections of *Rhodococcus, Gordonia, Nocardia, Dietzia, Tsukamurella,* and *Nocardioides* whole cell compositions.

The state of the prior art concerning autoimmunity indicates that the mechanisms of occurrence and treatement are multifactorial (Textbook of Medicine, pages 126-163, 15th edition, 1979) and that one composition does not treat or prevent all such immune disorders.

Therefor, there is a lack of predictability in the art that one composition, such as claimed, will treat or prevent any/all autoimmune diseases or autoimmune disorders.

The amount of direction/guidance/examples present in the instant specification is insufficient for the extremely broad scope of the instant claims. The majority of the examples in the specification are drawn to composition preparations and their effect on skin reactions, toxicity, T-cell activity alterations, and immunity inductions. The only examples of treatment present in the specification are drawn to a vascular disease model in rats following angioplasty, and mycarditis.

Thus, the quantity of experimentation necessary for the extremely broad scope of the instant claims constitutes merely an invitation to experiment without a reasonable expectation of success.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 12 and 13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 18 and 19 of copending Application No. 10/526,228. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to the same general method, i.e., treating or preventing or immunizing a subject against a condition/disorder/disease by administration of a composition comprising whole cells of one more of the genera *Rhodococcus, Gordonia, Dietzia, Tsukamurella,* or *Nocardioides.*

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Matson et al (U.S. Pat. No. 4,599,310, July, 1986).

The claims are drawn to a composition in the manufacture of a medicament. The remaining recitations in the claims are merely intended use of the medicament and therefore place no patentability on the composition.

Matson et al teach compositions comprising a *Nocardioides* sp. Strain C49,009 in the manufacture of a medicament (col. 3, lines 1-55; Table 1, col. 6, line 65 to col. 8, line 64; Example 1, claims 1-3).

Conclusion

16. No claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 7:30 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Jeffrey Siew, can be reached on (571)272-0787.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

March 3, 2007